Office-Supreme Court, U.S.
FILED
MAR 8 1963
JOHN F. DAVIS, CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1962

No. 911

MILLPAX, a Corporation, and
ROY F. PAXTON, an Individual, *Petitioners,*

v.

UNITED STATES OF AMERICA, *Respondent*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

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INDEX

	Page
Opinions Below	1
Jurisdiction of This Court	2
Questions Presented for Review	3
The Statute Involved	4
Statement of the Case	4
Reasons for the Granting of the Writ	9
Argument	11
Conclusion	18
Appendix	1a

STATUTES CITED

Federal Food, Drug, and Cosmetic Act, June 25, 1938, c. 675, Sec. 1, 52 Stat. 1040 (21 U.S.C. 301 et seq.) 3, 4, 7, 9, 11, 12, 13

REGULATIONS

General Regulations, Food, Drug, and Cosmetic Act, Title 21, Code of Federal Regulations, Part 1 (Sec. 403(j)), 52 Stat. 1048; 21 U.S.C. 343(j) 11

TABLE OF CASES CITED

Hansford v. United States, 112 U.S. App. D.C. 359, 303 F. 2d 219 17
Johnson v. United States (CCA DC, No. 16890, not yet reported) 10
Sherman v. United States, 356 U.S. 369 (1958) 10, 16
Sorrells v. United States, 287 U.S. 452 16
United States v. Johnson, 177 Fed. 313, 211 U.S. 488, 31 S. Ct. 627, 55 L. Ed. 823 14
United States v. Sferas, 210 F. 2d 69, 71 (C.A. 7, 1954), cert. den. 347 ..... 10, 15
United States v. Sherman, 200 F. 2d 880 (2d Cir. 1952) 17
United States v. 10 Cartons . . ., 152 F. Supp. 360 (W.D. Pa. 1957) 12
V. E. Irons et al. v. United States, 244 F. 2d 34 (C.A. 9, 1957), cert. den. 354 U.S. 923 12

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To the Honorable, the Chief Justice of the
United States and the Associate Justices of
the Supreme Court of the United States:

Petitioners, Millpax, Inc., a corporation, and Roy F. Paxton, an Individual, respectfully pray that a writ of certiorari issue to the United States Court of Appeals for the Seventh Circuit to review a final judgment of that Court, affirming judgments of the United States District Court, Southern District of Illinois, Southern Division, convicting Defendants on Counts III and V, of a five count Indictment.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Seventh Circuit, dated January 15, 1963, is not yet reported, but a copy thereof is attached to this petition as Appendix hereto.

The judgments of the United States District Court, Southern District of Illinois, Southern Division, are found at pages 135-138, Appendix to Brief for Defendants-Appellants, and also filed here.

JURISDICTION

Petition for rehearing was filed by the Defendants-Appellants with the United States Court of Appeals for the Seventh Circuit, on January 24, 1963. By order dated February 21, 1963, a copy of which is attached to this petition as Appendix hereto, the appellate court changed its Opinion of January 15, 1963, in certain respects as indicated, but denied petition for rehearing.

Motion for stay of mandate for a period of 30 days, pending application for writ of certiorari to the Supreme Court of the United States, was filed by Defendants-Appellants with the United States Court of Appeals for the Seventh Circuit, on February 26, 1963. Pursuant thereto, the Court by Order entered February 27, 1963, granted Motion for stay of mandate for a period of 20 days only.

Jurisdiction is conferred on the Supreme Court of the United States by U.S.C. Title 28, Section 1254, to review this cause by writ of certiorari.

QUESTIONS PRESENTED FOR REVIEW

Five important federal questions presented herein are:

1. Whether a vendor of a food product for special dietary purposes, as so defined by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), can be held answerable for the unsolicited praise of users of the product, even though mistaken, where the vendor did not make use of the commendations in furthering the sale and distribution of the product?

2. Whether a vendor of a food product is obliged to take positive action to negate or disclaim such praise, where the commendations are incorporated in a magazine article, the preparation and publication of which were without the knowledge or sanction of the vendor?

3. Whether government agents, employing the stratagem of posing as ordinary customers, in ordering such product by mail for faked ailments, and making reference to the magazine article, aforesaid, imputes to the vendor therapeutic claims for the product, thereby classifying the preparation ipso facto into the category of a drug?

4. Whether the conclusion by an appellate court that an accused would have committed an act violative of a federal statute, is sufficient to support a conviction for the violation of that provision of the Act which prohibits the introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded? (Sec. 301(a), Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301 et seq.).

5. Whether an appellate court can properly refuse to consider for the first time on the appellate level the question of entrapment as a matter of law, even though it results in a miscarriage of justice?

THE STATUTE INVOLVED

The statute involved in the determination of the questions is the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).

STATEMENT OF THE CASE

This cause concerns a food product for special dietary use, registered as such in the U. S. Patent Office, and neither deleterious nor harmful to consumers. It is properly labeled in accordance with the labeling requirements of the Act, as a food product for special use.

The first question concerns the issue of whether a vendor of a product can be held answerable for the unsolicited praise of the product, if the vendor does not exploit such commendations in promoting the sale of the product.

In March, 1960, one Don Machem prepared, and caused to be published in a magazine called the "Herald of Health," an article containing in substance praises by users of the product (known as "Millrue"), as to the value of this preparation in the instance of certain human ailments. The Petitioners herein were without knowledge of the preparation of this magazine article, nor were they aware of its existence until it appeared in the aforesaid publication. There is no evidence in the record that the claims in the article were used by the Petitioners in the labeling for Millrue.

The second question concerns the character of the responsibility, if any, that a vendor of a product is obliged to assume, for the mistaken praise of users of the product in the instance of human ailments, where such commendations were not exploited by the vendor for its benefit.

When the Petitioners herein were aware of the published article, aforesaid, they immediately took action to negate or disclaim the claims appearing in the article for the product "Millrue", by directing counsel to prepare a letter of disclaimer, in the text quoted below, which document was mailed to those who were prompted by the article to inquire about, and/or order Millrue:

> Many thanks for your letter and order and it is regretted that Mr. Paxton cannot write to you personally as the mail has been tremendous and the Company is a small one.
>
> Your interest in the article referred to is natural, but terming the product a 'blood purifier' therein is a misnomer. To 'purify' connotes that as to any particular substance it is freed from extraneous matter or from anything that debases, pollutes, or contaminates it. The blood may be variable through bodily functions, or malfunctions, and by ingestion, deficiencies when existent may be aided.
>
> If you will again read the article referred to which was written by Don C. Matchan, you will find that no claim is made that the product cures anything, either by the writer or the manufacturer. Any person may state what he believes the product has done or has not done for him, and any person is free to draw his own conclusion therefrom.
>
> If you still desire to order please advise by return mail, otherwise your money will be returned to

you, as there is no desire by the manufacturer to sell this product under false pretenses.

The third question concerns the stratagem employed by two government agents, posing as ordinary customers, who addressed letters to the Petitioners herein, referring to the magazine article, aforesaid, and ordering Millrue for faked ailments.

Agent Charles A. Armstrong, an inspector of the Federal Food and Drug Administration, addressed a letter on May 2, 1960, from Memphis, Tennessee, to the Petitioners in Carlock, Illinois, as follows:

> I read about your cancer cure—Millrue—in the March, 1960 issue of Herald of Health.
>
> I am enclosing a $10 money order for two bottles of the Millrue.
>
> I have just been told that I have cancer of the throat that cannot be cured without an operation, but I'd rather take medicine if it can cure me also.

Upon receipt of a letter of disclaimer, above quoted, Agent Armstrong replied:

> I received your letter of May 6.
>
> Please send me the two bottles of Millrue that I ordered.

Agent Jack B. Forbragd, an inspector of the Federal Food and Drug Administration, addressed a letter on May 6, 1960, from San Francisco, California, to the Petitioners herein, as follows:

> A good friend just showed me a wonderful article in Herald of Health Magazine about how you make a herb medicine to cure cancer called Millrue. I have stomach pains and constipated and I am sure it is cancer because my neighbor had it just like

> this and they just sewed her up and sent her home to die. I don't know much tax is there so will send 20 cents like it is in California. Please send a bottle of Millrue right away.

The record is in conflict as to whether Agent Forbragd received Petitioners' disclaimer reply, or whether this government representative in an alleged telephone conversation with the Petitioners herein insisted on the shipment of the product despite Petitioners' disclaimer during the conversation that "we do not sell any medicine for any disease of any kind."

Based solely on the above exchange of communication between the government agents and the Petitioners, the government insisted, and the United States Court of Appeals for the Seventh Circuit concluded, that the letter of disclaimer "was framed with the intention of drawing a cloak of legality around defendants' transactions," and that it was "obvious that defendants intended to be understood as adopting as their own the magazine testimonials." Further, according to the appellate court, it was "the intention of the defendants * * * to have prospective purchasers regard it as a drug and so use it; hence, their own actions classified Millrue as a drug."

The fourth question concerns the degree of positiveness of the Act necessary to constitute a violation of Sec. 301(a) of the Federal Food, Drug, and Cosmetic Act, as Amended, (21 U.S.C. 301 et seq.), which prohibits the introduction into interstate commerce of any drug that is misbranded.

The essential elements for the violation are therefore that the product be a drug, in a misbranded state, and that interstate commerce must be established. Despite

these essentials, the appellate court herein, in its amended opinion (Appendix hereto), stated:

> We believe the surrounding circumstances brought out in the evidence support the conclusion that defendants would have sold the misbranded Millrue regardless of who the purchasers were, and the fact that the government agents used a ruse to conceal their identity does not require a different conclusion.

The record in the case fails to include a scintilla of evidence of any positive sale on the part of Petitioners, of the product to any ordinary purchasers in a misbranded state.

The fifth question to be considered, concerns entrapment as a matter of law.

The ruse adopted by the government agents herein, was prompted solely by the praises of Millrue users, appearing in a magazine article, neither prepared nor published by Petitioners, nor made use of in furthering the sale of the product.

The sole practices complained of by the government are limited to the two transactions between the Petitioners and two government agents, who induced the Petitioners by stratagem to sell Millrue. No evidence was developed that the Petitioners were otherwise engaged in criminal activity. On the contrary, the only acts complained of were those, the commission of which, was induced by the ruse of the agents. The Petitioners, at the appellate level, raised for the first time the defense of entrapment as a matter of law on the ground that otherwise the result would lead to a miscarriage of justice. The appellate court concluded in this re-

spect, that the issue of entrapment was properly left to the jury. (Opinion, p. 7, Appendix hereto).

The Petitioners herein were found guilty after trial by jury on three counts of a five-count indictment charging them with the misbranding of a drug known as "Millrue," in that the labeling failed to bear adequate directions for use, as required by Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 352 (f)(1), and with causing the introduction or delivery for introduction into interstate commerce of such preparation, so labeled, in violation of Section 301(a) of the Act, 21 U.S.C. 331(a), which prohibits the introduction or delivery for introduction into interstate commerce of any drug that is misbranded.

The judgment entered by the District Court convicting defendants on Counts III and V, of the Indictment, which Counts concerned the Armstrong and Forbragd transactions, respectively, was affirmed by the United States Court of Appeals for the Seventh Circuit, the Court reversing the conviction by the lower court on Count IV.

REASONS FOR GRANTING OF THE WRIT

One primary reason relied upon for the allowance of this Petition for a Writ of Certiorari is that this case raises important questions of federal law concerning the interpretation of Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, as Amended, 21 U.S.C. 301, et seq. This section of the Act provides that a drug is deemed to be misbranded unless its labeling bears adequate directions for use. The principal question concerned in the case at bar is whether the acts of

government agents posing as ordinary customers, can be imputed to a vendor so as to constitute therapeutic claims for the product involved.

A second primary reason relied upon for the allowance of this Petition for a Writ of Certiorari is that the decision of the court below is in conflict with applicable decisions of this Court, and in conflict with the decision of another court of appeals on the same matter. The court below, in its decision with respect to the instant cause, held the Petitioners herein answerable for the mistaken praises of others as to their product, despite the fact that the Petitioners did not make use of these praises in promoting the sale of the preparation. An applicable decision by the Supreme Court of the United States established that a shipper cannot be made answerable for the mistaken praise of others as to the product concerned, if such praise is not exploited to the shipper's profit. *United States* v. *Johnson,* 177 Fed. 313, 221 U.S. 488, 31 S. Ct. 625, 55 L. Ed. 823.

A third primary reason relied upon for the allowance of this Petition for a Writ of Certiorari is that the appellate court below refused to consider as an assigned error the defense of entrapment as a matter of law, for the first time on appeal, despite the fact that the result would lead to a miscarriage of justice. *United States* v. *Sferas,* 210 F.2d 69, 71 (C.A. 7, 1954), cert. den. 347.

Entrapment, as a matter of law, was established in the present cause, and the Petitioners, otherwise innocent, were induced to commit the acts complained of. *Sherman* v. *United States,* 356 U.S. 369, 373 (1958). Also, *Johnson* v. *United States* (U. S. Court of Appeals for the District of Columbia Circuit, No. 16890, decided Feb. 14, 1963), not yet reported.

ARGUMENT

The Petitioners herein manufactured and sold a food product known as Millrue, and so registered as such with the U. S. Patent Office. Its label satisfied the requirements of the Federal Food, Drug, and Cosmetic Act, as Amended (21 U.S.C. 301, et seq.). Such a product can properly be used in the dietary treatment of disease. (Section 1.11, General Regulations, Food, Drug, and Cosmetic Act, Title 21, Code of Federal Regulations, Part I (Sec. 403(j), 52 Stat. 1048; 21 U.S.C. 343(j)).

The Federal Food and Drug Administration initiated its action against the Petitioners herein as a result of the article appearing in the March 1960 issue of the magazine "Herald of Health." The District Court herein refused to admit into evidence the context of this article. The stratagem employed by the Agency took the course of approaches by two government agents, posing as ordinary customers with fictitious ailments, addressing letters to the Petitioners herein, referring to the magazine article and ordering Millrue for certain diseases.

The government was confronted with the problem of establishing that Millrue, although a food product properly labeled as such, was being introduced into interstate commerce by the Petitioners as a drug.

The government did not contend that the exchange of communications between the government agents and the Petitioners herein constituted labeling. Labeling, as defined by the Act means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. (Sec. 201(1), Federal Food, Drug, and Cos-

metic Act, as Amended, 21 U.S.C. 301 et seq.). The government did, however, regard this exchange of communications as a highly relevant source "that may be considered in determining the conditions and purposes for which Appellants sell Millrue." That the Court may look to all relevant sources in order to ascertain what was the intended use of a product, is not denied, nor is it the argument of the Petitioners herein that relevant sources are confined to labels on the product or its labeling. Relevant sources were referred to in *V. E. Irons et al* v. *United States*, 244 F. 2d 34, 44 (C.A. 1, 1957), cert. den. 354 U.S. 923, as oral representations to users, and printed circulars. In *United States* v. *10 Cartons* . . . 152 F. Supp. 360, 368 (W.D. Pa. 1957), relevant sources were characterized as impressions created by oral representations, advertisements, and other sources upon the person to whom the representations are directed.

In the cause at bar, Agents Armstrong and Forbragd, by initially addressing the Petitioners herein, as aforesaid, set in motion forces which the government considered as creating the impression that Millrue was intended by the Petitioners for use in the treatment of diseases.

The record contains no proof that such was the impression of ordinary customers. Try as it might, the government failed to produce a single ordinary customer who could testify of such an impression. The case then turned on the efforts of two government agents who faked diseases, and ordered Millrue for these ailments with full knowledge that the product was without value in the treatment of diseases. Despite a disclaimer by the Petitioners herein that Millrue

would not cure anything, the government convinced the appellate court that the Petitioners had thereby given the impression that the product was intended for use in the treatment of disease.

Proceeding on that theory, the appellate court herein, held in its amended decision—

> We believe the surrounding circumstances brought out in the evidence support the conclusion that defendants would have sold the misbranded Millrue regardless of who the purchasers were, and the fact that the government agents used a ruse to conceal their identity does not require a different conclusion. (Appendix hereto).

Even positive expressions by a vendor which give rise to the question of intent, in a case such as this is, must not be interpreted through the minds of experts, but rather, the effect of such impressions, if any are created for which the creator is responsible, must be interpreted through the minds of ordinary customers.

Agents Armstrong and Forbragd were neither savants nor dolts, and they did not purchase Millrue in the belief that this product had curative properties in the treatment of diseases in man.

The Federal Food, Drug, and Cosmetic Act, as Amended, 21 U.S.C. 301 et seq.), is a criminal statute that should be strictly construed and applied. The Congress, at no time during the debates concerning the Act, asserted or pretended that it was proposed to reach the matter of holding manufacturers and vendors of preparations to criminal liability for misstatements of others as to the curative or remedial effects of the preparations; that had such been the intent, apt words, both in the title and body of the Act, could and should

have been easily employed to indicate such purpose, and not leave it to the courts by strained construction to read it into the statute. *United States* v. *Johnson*, supra, 177 Fed. 313, 221 U.S. 488, 31 S. Ct. 627, 55 L.Ed. 823.

The Petitioners herein recognize that the *Johnson* case primarily held that the original misbranding provisions of the 1906 Act did not cover therapeutic claims, which decision brought about the Sherley amendment of August 23, 1912, prohibiting the making of false or fraudulent statements on labels and packages regarding the curative or therapeutic effect of the article being sold or any of its ingredients. The *Johnson* case did however establish the doctrine, currently recognized, that manufacturers and vendors of preparations are not criminally liable for the praises of others, even though mistaken, where such commendation was not exploited by the manufacturers and vendors for their profit.

Even had the forces set in motion by the government agents resulted in creating the impression that Millrue had value in the treatment of disease, the consequence of such action on the part of the government cannot be imputed to the Petitioners, so as to establish intendment on their part that Millrue had therapeutic value.

The exchange of communications between Agents Armstrong and Forbragd and the Petitioners herein, as aforesaid, cannot therefore be regarded as a relevant source for the purpose of determining the conditions and purposes for which Petitioners offered their product.

Nor can the article appearing in the magazine "Herald of Health," be regarded as a relevant source, since

the praises therein were not used in any manner by the Petitioners in the distribution of Millrue.

The Petitioners herein were not aware of the preparation and publication of the magazine article. When they learned of the context of the article after its publication, the Petitioners immediately instructed local counsel to prepare a disclaimer which was mailed to those who inquired about and/or ordered Millrue as a result of the magazine article.

The government was unable to minimize the true meaning of the positive assertion in the disclaimer that "no claim is made that the product cures anything, either by the writer, or the manufacturer." The government did successfully convince the appellate court that the "statement in the disclaimer letter that 'Any person may state what he believes the product has done or has not done for him, and any person is free to draw his own conclusion therefrom,' within the factual context present here, does not shield defendants from the consequences of their wilful acts." Thus, local counsel, in incorporating the above quoted sentence in the disclaimer, merely expressed a freedom that is enjoyed in this Country, but the appellate court regarded the disclaimer as being "framed with the intention of drawing a cloak of legality around defendants' transactions."

As to the question of entrapment, the Petitioners submit that injustice resulted from the failure of the trial court to rule that entrapment had been established as a matter of law, and that the refusal of the appellate court to consider this question for the first time on appeal leads to a miscarriage of justice. *United States* v. *Sferas*, supra, 210 F.2d 69 (7th Cir. 1954).

The doctrine of entrapment is revealed in the following statement of the Supreme Court of the United States, and is pertinent to the instant cause:

> The defense is available, not in the view that the accused though guilty may go free, but that the Government cannot be permitted to contend he is guilty of a crime where the government official are the instigators of his conduct.

Sorrells v. *United States,* 287 U.S. at 452, and *Sherman* v. *United States,* supra, 356 U.S. 369 (1958).

In the present cause, the acts complained of, which ultimately were the sole basis for the appellate court decision, were the two transactions with Petitioners by Agents Armstrong and Forbragd of the government. Despite gross annual sales of some fifty to sixty thousand dollars of Millrue, the government was obliged to rely on the two transactions, aforesaid, in the prosecution of this case. And, in those two transactions, government officials were themselves the instigators of the conduct of Petitioners.

In all of the thousands of dollars of sales of Millrue to ordinary customers, not challenged by the government, no therapeutic claims for the product were made by the Petitioners, and in these sales, the product so distributed, was a dietary food supplement, properly labeled as such. Thus, Petitioners were neither engaged in criminal activity at the time the government instituted its stratagem, nor were the Petitioners awaiting any propitious opportunity to commit the offense of making therapeutic claims for Millrue, thereby transferring a food product into the category of a drug, and introducing a misbranded drug into interstate commerce.

That Petitioners were not awaiting an opportunity to commit the offense charged, nor were they predisposed to do so, is further evidenced by the efforts of Petitioners to disclaim the commendations appearing in the magazine article. Even in the two transactions complained of by the government, the sale of Millrue in each of these transactions was not consummated until disclaimers had been sent, or made known, to each inquirer, and re-orders submitted on the basis of the disclaimers.

In *Hansford* v. *United States*, 112 U.S. App. D.C. 359, 303 F.2d 219, the statement of Judge Learned Hand in *United States* v. *Sherman*, 200 F.2d 880 (2d Cir. 1952), was quoted as follows:

> In such cases two questions of fact arise: (1) did the agent induce the accused to commit the offence charged in the indictment; (2) if so, was the accused ready and willing without persuasion and was he awaiting any propitious opportunity to commit the offence. On the first question the accused has the burden; on the second the prosecution has it.

It is most significant that in the instant case, Petitioners were committing no federal offense in the sale of Millrue immediately prior to the ruse of the government agents. In fact, the sale of Millrue as a dietary food supplement, complied with all pertinent federal statutes. The offense charged was the alleged sale by Petitioners of Millrue for the treatment of disease. Such a sale on that premise, even if such premise was imputed to Petitioners, was induced by government officials. Unlike the ordinary narcotic cases, where the sale of such product is illegal, the sale of a harmless food supplement, as such, is legal, unless and until the

vendor makes therapeutic claims for the product and that use is not included in the product's labeling. Petitioners made no such claims to the two government officials. Rather, these officials set in motion the claims complained of, induced the Petitioners to sell Millrue under those circumstances, and then charged the commission of an offense.

The very preparation of a disclaimer by the Petitioners, and its circulation as aforesaid, negates the premise that the Petitioners were awaiting a propitious opportunity to sell Millrue as a drug.

Nor while Petitioners might have been ready and willing to sell Millrue to the government agents as a food supplement, Petitioners were clearly induced to commit the offense charged, and the origin of the criminal design in this case was with the government.

CONCLUSION

For the reasons stated, and under the authorities cited, it is submitted that the decision of the United States Court of Appeals for the Seventh Circuit was and is in error, in affirming the judgment entered by the District Court convicting defendants on Counts III and V, of the Indictment, and that this Petition for a Writ of Certiorari to that Court to review its action in so holding, as herein sought, is well founded in fact and in law and should be granted.

Respectfully submitted,

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